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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/541,094	03/31/00	ST. GEORGE-HYSLOP	P 1034/1F812-U

HM12/0521

DARBY & DARBY P C
805 THIRD AVENUE
NEW YORK NY 10022

EXAMINER	
PENN, M	
ART UNIT	PAPER NUMBER
1633	9

DATE MAILED: 05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/541,094	ST. GEORGE-HYSLOP ET AL.	
	Examiner	Art Unit	
	Michael G. Penn	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claims 1-45 are pending and under consideration in the instant office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to an amino acid sequence encoding PAMP, classified in class 435, subclass 350.

II. Claims 7-17, and 29, drawn to a nucleic acid sequence encoding PAMP, and methods of production thereof, classified in class 536, subclass 23.5.

III. Claims 18-24, and 42, drawn to transgenic animals containing PAMP, classified in class 800, subclass 8+.

IV. Claims 25-28, and 30, drawn to an animal containing a nucleic acid that expresses an endogenous PAMP, classified in class 800, subclass 8+.

V. Claims 31-36, 43-45 drawn to systems for measuring PAMP activity, and methods for identifying modulators of PAMP activity classified in class 204, subclass 450+.

VI. Claims 37-41, drawn to methods for detecting variations in the PAMP gene, classified in class 435, subclass 6.

<u>The inventions are distinct, each from the other because of the following reasons</u>:

Invention I is patentably distinct from Invention II because Invention I is drawn to an amino acid sequence encoding PAMP, whereas Invention II is drawn to a nucleic acid sequence encoding PAMP. These are both distinct inventions, as the nucleic acid

does not require the amino acid sequence for use or production. Furthermore, wholly different methods of production and use for each of these would be practiced, and a divergent search would be required. Therefore, restriction is proper.

Invention I is patentably distinct from Inventions III and IV because Invention I is drawn to amino acid sequences encoding PAMP, whereas Invention III is drawn to transgenic animals that comprise a transgene encoding PAMP, and Invention IV is drawn to animals that contain a nucleic acid encoding endogenous PAMP. Different methods and reagents are necessary to practice each of these inventions. For example, amino acid sequences are not necessary for the generation of a transgenic mouse, or for the mutation of a mouse that expresses PAMP. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Invention I is patentably distinct from Inventions V and VI because Invention I is drawn to an amino acid sequence encoding PAMP, whereas Inventions V and VI are drawn to methods or systems for measuring PAMP activity or identifying modulators of PAMP activity. These are both distinct inventions, as the amino acid sequence is not required to practice the other inventions. Furthermore, different methods and reagents are necessary to practice each of these inventions, and divergent fields of search are required. Therefore, restriction is proper.

Invention II is patentably distinct from Inventions III and IV because Invention II is drawn to nucleic acid sequences encoding PAMP and methods of producing PAMP, whereas Invention III is drawn to transgenic animals that comprise a transgene encoding PAMP, and Invention IV is drawn to animals that contain a nucleic acid

encoding endogenous PAMP. Different methods and reagents are necessary to practice each of these inventions. For example, *in vitro* generation of a cell transfected with a vector encoding PAMP requires very different techniques and reagents than would successful generation of a mouse containing a transgene encoding PAMP. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Invention II is patentably distinct from Inventions V and VI because Invention II is drawn to the nucleic acid sequences encoding PAMP and methods of producing PAMP, whereas Inventions V and VI are drawn to methods or systems for measuring PAMP activity or identifying modulators of PAMP activity. Different methods and reagents are necessary to practice each of these inventions. *In vitro* generation of a cell that produces PAMP requires wholly different techniques and reagents than those required for the optimization and performance of methods for measuring protein activity, or methods for identifying modulators of a protein. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Invention III is patentably distinct from Invention IV because Invention III is drawn to transgenic animals containing PAMP, whereas Invention IV is drawn to an animal containing a nucleic acid that expresses endogenous PAMP. These are distinct inventions because Invention IV can read on an animal that expresses PAMP without any intervention from man, and techniques designed to alter that expression, whereas Invention III involves genetic manipulation and generation of a transgenic animal that normally does not contain the gene for PAMP. Therefore, restriction is proper.

Inventions III and IV are patentably distinct from Invention V because Invention III is drawn to transgenic animals that comprise a transgene encoding PAMP and Invention IV is drawn to animals that contain a nucleic acid encoding endogenous PAMP, whereas Invention V is drawn to methods or systems for measuring PAMP activity or identifying modulators of PAMP activity. Different methods and reagents are necessary to practice each of these inventions. Successful generation of a mouse containing a transgene encoding PAMP requires wholly different techniques and reagents than those required for the optimization and performance of methods drawn to measuring protein activity or methods for identifying modulators of a protein. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Invention III is distinct from Invention VI because Invention III is drawn to transgenic animals that comprise a transgene encoding PAMP, whereas Invention VI is drawn to methods for detecting variations in the PAMP gene. Different methods and reagents are necessary to practice each of these inventions. For example, detection of variations in the PAMP gene would require different techniques and reagents that are not required for generation of a transgenic animal, such as specific hybridization assays and protocols optimized for gene identification. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Invention IV is patentably distinct from Invention VI because Invention IV is drawn to animals that contain a nucleic acid encoding endogenous PAMP, whereas Invention VI is drawn to methods for detecting variations in the PAMP gene. Different

methods and reagents are necessary to practice each of these inventions. For example, detection of variations in the PAMP gene would require different techniques and reagents that are not required for alteration or chemical mutation of the PAMP gene in an animal that contains the PAMP gene, such as specific hybridization assays and protocols optimized for gene identification. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Invention V is patentably distinct from Invention VI because Invention V is drawn to systems for measuring PAMP activity or methods for identifying modulators of PAMP activity, whereas Invention VI is drawn to methods for detecting variations in the PAMP gene. Different methods and reagents are necessary to practice each of these inventions. For example, detection of variations in the PAMP gene would require different techniques and reagents that are not required for measurement of PAMP activity, such as nucleic acid probes, PCR methodologies, or other molecular biology techniques. Furthermore, divergent fields of search are required for each of these inventions, therefore restriction is proper.

Note further that this application contains claims directed to patentably distinct species of the claimed inventions.

Should applicant elect invention I, applicant is further required to elect from SEQ ID NO: 14—human PAMP (in claim 2), SEQ ID NO: 16—mouse PAMP (in claim 3), SEQ ID NO: 18—*D. Melanogaster* PAMP (in claim 3), or SEQ ID NO: 12—*C. elegans* PAMP (in claim 3).

Should applicant elect Invention II, applicant is further required to elect from SEQ ID NO: 13—human PAMP (claim 8), SEQ ID NO: 15—mouse PAMP (claim 9), SEQ ID NO: 17—*D. Melanogaster* PAMP (claim 9), or SEQ ID NO: 11—*C. elegans* PAMP (claim 9).

Should applicant elect Invention III, applicant is further required to elect from human presenilin-1, human presenilin-2, or human β-amyloid precursor protein (claim 24).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4-7, 10-21, 23, 25-45 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Penn who can normally be reached on Monday through Friday from 8:00 am to 4:30 p.m. at (703) 308-2454.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, who can normally be reached on Monday through Friday from 9:00 am to 5:30 p.m. at (703) 305-3015.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael G. Penn

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600